Prospective evaluation of new duplex criteria to identify 70% internal carotid artery stenosis

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Purpose: Large multicenter trials (North American Symptomatic Carotid Endarterectomy Trial, European Carotid Surgery Trial) have documented the benefits of carotid endarterectomy for treating symptomatic patients with ≥70% stenosis of the internal carotid artery. Although color-flow duplex scanning has become the preferred method for noninvasive assessment of internal carotid artery disease, no criteria have been generally accepted to identify this subset of patients. We previously reported a retrospective series to establish such criteria. This study details our results when these criteria were applied prospectively.

Methods: Carotid color-flow duplex scans were compared with arteriograms in 457 patients who underwent both studies. Criteria for ≥70% internal carotid artery stenosis were peak systolic velocity >130 cm/sec and end-diastolic velocity >100 cm/sec. Internal carotid arteries with peak systolic velocity <40 cm/sec in which only a trickle of flow could be detected were classified as preocclusive lesions (95% to 99% stenosis). Arteriographic stenosis was determined by comparing the diameter of the internal carotid artery at the site of maximal stenosis to the diameter of the normal distal internal carotid artery.

Results: Internal carotid artery stenosis of ≥70% was detected with a sensitivity of 87%, specificity of 97%, positive predictive value of 89%, negative predictive value of 96%, and overall accuracy of 95%. Eighty-seven percent of 70% to 99% stenoses were correctly identified. False-positive errors (n = 10) were attributed to contralateral internal carotid artery occlusion or high-grade (>90%) stenosis (n = 5) and to interpreter error (n = 1); no explanation was apparent in the other four. Eleven of 12 false-negative examinations occurred in patients with 70% to 80% internal carotid artery stenosis.

Conclusions: In our laboratories, prospective application of the above velocity criteria identified internal carotid artery stenosis of ≥70% with a reasonably high degree of accuracy. Errors occurred when stenoses were borderline and in patients with severe contralateral disease. With suitably modified velocity criteria, color-flow duplex scanning remains the most reliable noninvasive method for identifying symptomatic patients who are candidates for carotid endarterectomy. (J VASC SURG 1996;23:254-62.)

Color-flow duplex scanning (CFS) has become the most widely used noninvasive method for assessing extracranial cerebrovascular occlusive disease. Stenotic lesions are identified and quantified by analyzing Doppler velocity spectra in combination with real-time B-mode and color-flow images of these vessels. Interpretation of CFS findings is commonly based on criteria that categorize internal carotid artery (ICA) stenosis into five degrees of severity: 0% to 15%, 16% to 49%, 50% to 79%, 80% to 99%, and 100% (or occlusion).[1] Differentiation between these degrees of stenosis is largely based on the measured velocity of blood flow within the ICA (Table I). The reliability of these criteria has been well documented.[2-4]

As confirmed by recent large randomized prospective trials,[5,6] carotid endarterectomy (CEA) reduces the incidence of subsequent neurologic events

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Table I. Traditional criteria for grading severity of ICA stenosis

% Stenosis category	*Velocity (cm/sec)*
0 to 15	PSV ≤100
16 to 49	PSV 101 to 120
50 to 79	PSV >120
80 to 99	PSV >120 & EDV ≥120
100	No flow detected

Table II. New criteria for grading severity of ICA stenosis

% Stenosis category	*Velocity (cm/sec)*
0 to 29	PSV ≤110
30 to 49	PSV 111 to 130
50 to 69	PSV >130
70 to 99	PSV >130 & EDV >100
100	No flow detected

in symptomatic patients with ICA stenoses of ≥70%. In these trials, patients were required to undergo arteriography to ascertain the degree of ICA stenosis. Noninvasive testing avoids the expense and risk of routine arteriography, and is therefore a potentially important method for identifying the subset of symptomatic patients who are likely to benefit from CEA. The traditional criteria for interpretation of CFS, however, were not specifically designed to diagnose 70% to 99% stenoses. Thus new criteria are required before this method can be used for screening purposes.

Our group previously published a retrospective analysis that established CFS criteria for stratifying ICA lesions into the categories of stenosis used in the prospective trials.[4] The ranges studied were 0% to 29%, 30% to 49%, 50% to 69%, 70% to 99%, and occlusion. Receiver operator characteristic curves were constructed to identify velocity criteria that best predicted each of these categories (Table II). For the 70% to 99% range, a peak systolic velocity (PSV) of >130 cm/sec plus an end-diastolic velocity (EDV) of >100 cm/sec provided the best overall accuracy (95%), with sensitivity of 81%, specificity of 98%, positive predictive value (PPV) of 89%, and negative predictive value (NPV) of 96%. This report details our results when these same criteria were applied prospectively. We also considered a small group of patients with preocclusive lesions (95% to 99% diameter stenosis or "string signs") in whom velocities were spuriously low because of decreased ICA blood flow.[7] Characteristics other than ICA velocity were necessary to identify these stenoses.

MATERIALS AND METHODS

From December 6, 1993, through March 17, 1995, we performed 3822 carotid CFSs in two accredited noninvasive vascular laboratories affiliated with the Southern Illinois University School of Medicine. Examinations were performed with either a Quantum 2000 (Siemens Medical Systems, Issaquah, Wash.) or Philips P700 (Philips Medical Systems, Santa Ana, Calif.) machine. A standard scanning technique was followed. B-mode and color-flow images of the common, external, and internal carotid arteries were obtained in longitudinal and transverse planes. Doppler velocity spectra were recorded from each of these vessels with the angle of insonation as close to 60 degrees as possible. The highest PSV and EDV in each vessel were noted. All CFSs were preserved on both hard copy and videotape and were reviewed daily by vascular surgery fellows and attending staff.

At the time of initial reading, all ICAs were prospectively assigned to a stenosis category on the basis of the velocity criteria identified by our previous retrospective analysis[4] or on characteristics associated with preocclusive lesions.[7] Preocclusive lesions were diagnosed if, after a careful search, only a trickle of low-velocity flow (PSV <40 cm/sec) could be detected on the color-flow image of the ICA lumen. Features of the common carotid artery (CCA) spectrum were also considered. Although dampening of the CCA waveform with low or absent flow in diastole indicates a high-resistance outflow and was often observed in patients with preocclusive lesions, it could not be used to differentiate between a tight stenosis and occlusion of the ICA. When the external carotid artery was widely patent and the ICA was occluded or nearly so, the spectrum from the CCA usually resembled the highly pulsatile waveform characteristic of the external carotid artery.

Arteriograms were ordered at the discretion of the attending physician, and were performed either in the radiology suite by radiology staff or in the cardiac catheterization laboratory by vascular surgery staff and fellows. Both standard cut-film and intraarterial digital subtraction techniques were used. At least two views of the ICA were available for comparison. The aortic arch and intracranial vessels were also routinely visualized. Intravenous digital subtraction studies were not performed.

Arteriograms were interpreted by vascular surgery fellows who were unaware of the results of the CFS. Arteriography was considered to be the gold standard for defining the degree of ICA stenosis,

Table III. Accuracy of CFS based on new velocity criteria alone (n = 414)

	Arteriogram (% stenosis)				
CFS (Velocity cm/sec)	*0 to 29*	*30 to 49*	*50 to 69*	*70 to 99*	*Total*
PSV ≤110	168	8	–	8	184
PSV 111 to 130	6	16	–	–	22
PSV >130, EDV ≤100	7	15	92	12	126
PSV >130, EDV >100	–	2	8	72	82
Total	181	41	100	92	414

Kappa = 0.767 ± 0.026; Perfect agreement = 84.1%.

Table IV. Accuracy parameters of CFS based on new velocity criteria alone

			Predictive value		
Velocity cm/sec	*Sensitivity (%)*	*Specificity (%)*	*Positive (%)*	*Negative (%)*	*Accuracy (%)*
PSV ≤110 vs >110	93.1	92.8	94.4	91.3	93.0
PSV ≤130 vs >130	95.8	89.2	88.5	96.1	92.3
EDV ≤100 vs >100	78.3	96.9	87.8	94.0	92.8

Derived from Table III. Based on 4 × 4 matrix.

which was calculated according to the method recommended by the Committee on Standards for Noninvasive Vascular Testing of the Joint Council of the Society for Vascular Surgery and the North American Chapter of the International Society for Cardiovascular Surgery.[8] The percentage of diameter reduction was determined by comparing the luminal diameter at the site of maximal stenosis with the diameter of the normal ICA immediately distal to the area of disease. Measurements were made using calipers and a finely calibrated ruler.

Results of CFS and arteriography were prospectively entered into a computerized data base. Mismatches between the severity of stenosis as measured by CFS and by arteriography were reviewed in bimonthly quality assurance conferences attended by vascular laboratory technicians and the vascular surgery staff. An attempt was made to determine a cause for the mismatches so that similar errors could be avoided in the future.

Of the 3822 carotid arteries scanned over the 15-month period, 457 arteries also were evaluated by arteriography within 1 month of the CFS. Sensitivity, specificity, PPV, NPV, and accuracy were determined for each category of stenosis. The κ value was calculated as a measure of correlation between the degree of ICA stenosis determined by CFS and by arteriography. (A κ value of 1.0 indicates perfect agreement, whereas a value of 0.0 indicates complete disagreement between the two examination results.)

RESULTS

Indications for CFS in the 248 patients included in this series were localizing symptoms (stroke, transient ischemic attack, amaurosis fugax) in 74 patients; nonspecific cerebrovascular symptoms (dizziness, ataxia, diplopia, drop-attacks, etc.) in 87 patients; asymptomatic (bruits or preoperative assessment) in 79 patients; and other symptoms in eight patients.

Table III shows the results obtained when the previously established CFS velocity categories were used as the sole method of predicting the degree of angiographic stenosis. Excluded from this analysis were 41 ICAs that were shown by arteriography to be totally occluded and 2 ICAs in which no flow was detected on CFS and that were thought to be occluded. Ninety-two of the 414 ICAs (22.2%) had stenoses of 70% to 99% as determined by arteriography. The new velocity criteria (PSV >130 cm/sec and EDV >100 cm/sec) identified these arteries with a sensitivity of 78.3%, specificity of 96.9%, PPV of 87.8%, NPV of 94.0%, and an accuracy of 92.8% (Table IV). For identifying 50% or greater stenosis (prevalence, 46.4%), the PSV >100 cm/sec criterion had a sensitivity of 95.8%., specificity of 89.2%, PPV of 88.5%, NPV of 96.1%, and an accuracy of 92.3% (Table IV). The overall κ value was 0.767 ± 0.026, and CFS and arteriographic findings agreed perfectly in 84.1% of studies. Results with the Quantum and Philips machines were equally reliable.

Seventy-two of 92 ICAs (78.3%) with 70% to 99% stenosis by arteriography were correctly iden-

Table V. Accuracy of CFS based on actual prospective interpretation (n = 457)

	Arteriogram (% stenosis)					
CFS (% stenosis)	*00 to 29*	*30 to 49*	*50 to 69*	*70 to 99*	*100*	*Total*
00 to 29	168	8	–	–	–	176
30 to 49	6	16	–	–	–	22
50 to 69	7	15	92	12	–	126
70 to 99	–	2	8	80	–	90
100	1	–	–	1	41	43
Total	182	41	100	93	41	457

Kappa (for 0% to 99% stenosis) = 0.796 ± 0.028; perfect agreement = 86.0%.
Kappa (for entire table) = 0.821 ± 0.022; perfect agreement = 86.9%.

Table VI. Accuracy parameters of CFS based on prospective interpretation

			Predictive value		
% Stenosis	*Sensitivity (%)*	*Specificity (%)*	*Positive (%)*	*Negative (%)*	*Accuracy (%)*
≤29 vs 30 to 99	96.6	92.8	94.5	95.5	94.9
≤49 vs 50 to 99	100.0	89.2	88.9	100.0	94.2
≤69 vs 70 to 99	87.0	96.9	88.9	96.3	94.7

Derived from Table V. Based on 4 × 4 matrix, excludes 100% column and row.

tified with the new velocity criteria (Table III). In 12 arteries with 70% to 99% arteriographic stenosis, CFS criteria predicted 50% to 69% stenosis on the basis of an EDV <100 cm/sec. Eleven of the one-category underestimations occurred in ICAs that were noted to have arteriographic stenoses between 70% and 80% (at the low end of the 70% to 99% range); only one of these ICAs had stenosis of 90%. All 12 scans were technically satisfactory. Eight ICAs with 95% to 99% angiographic stenoses were misclassified in the 0% to 29% stenosis category on the basis of PSVs that were less than 40 cm/sec (Table III). All of these arteries, however, had scans that showed only a trickle of flow, and all were prospectively classified as having string signs.

Table III also shows that an EDV >100 cm/sec correctly predicted 70% to 99% stenosis in 72 of 82 studies (87.8%). The degree of arteriographic stenosis was overestimated by one category in eight cases (9.8%) and by two categories in only two cases (2.4%). Five of the 10 overestimations occurred in patients with occlusion or high-grade (>90%) stenosis of the contralateral ICA. Interpreter error accounted for another overestimation; in this patient, the ICA EDV was misread due to incorrect positioning of the angle cursor. No clear explanation was found for the other four errors.

Table V includes data for total occlusions and compares the actual initial interpretations of CFS results with arteriographic findings. The eight string signs that were counted as misclassifications in the velocity analysis have been shifted to their proper place in the matrix because these scans were actually properly identified as representing high-grade stenoses. As shown in Table VI, the sensitivity of prospective CFS interpretations for identifying 70% to 99% stenosis was 87%. Other parameters of accuracy were essentially unchanged. All totally occluded ICAs were identified, for a sensitivity and NPV of 100%. Forty-one of the 43 ICA occlusions (95.4%) diagnosed by CFS were verified by arteriography. One false-positive diagnosis represented failure to locate an ICA with a low-grade stenosis, a technical error. The other false-positive error was due to failure to identify a slender residual channel in a 95% stenotic ICA with an ipsilateral middle cerebral artery occlusion.

Fig. 1 summarizes the accuracy of prospective CFS in terms of the percentages of studies in each category of stenosis that were overestimated, underestimated, and concordant according to arteriographic measurements. Predictions of total occlusion and low-grade stenoses (0% to 29%) were most likely to be accurate. Eighty-nine percent of the 70% to 99% predictions were confirmed by arteriography, but in 11%, CFS overestimated disease severity by one or two categories. Ten percent of ICAs thought to have 50% to 69% stenoses actually had lesions that fell in the 70% to 99% category.

An ICA-PSV/CCA-PSV ratio of 3.3 or greater

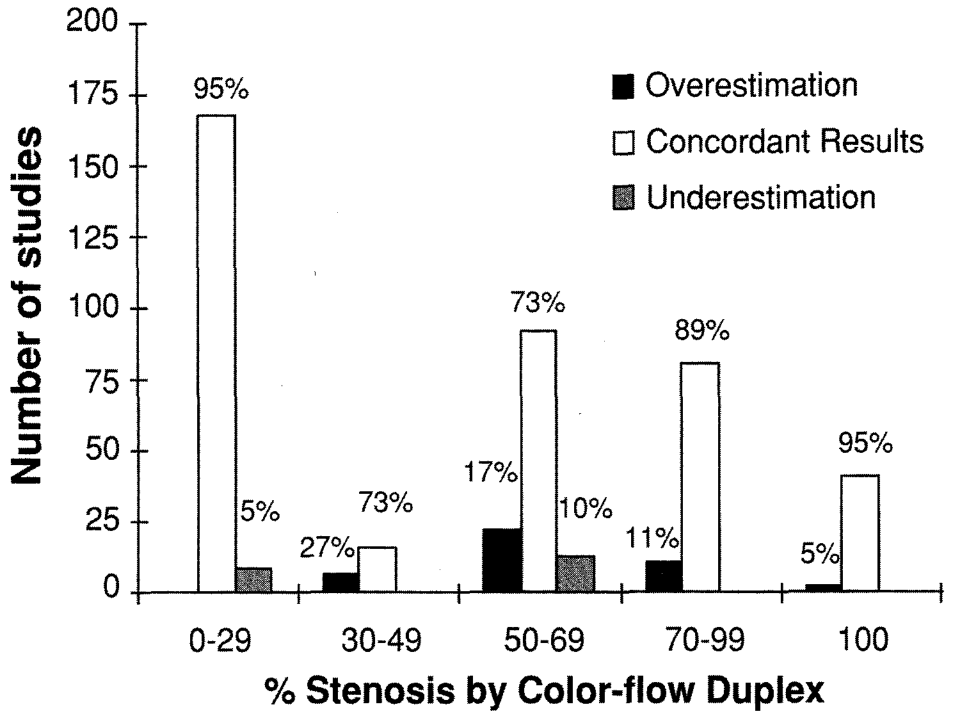

Fig. 1. Accuracy of CFS reading as compared with arteriography for each category of ICA stenosis. *Concordant results* indicates those studies for which the CFS and arteriographic assessments were in agreement. *Overestimations* and *underestimations* indicated those studies for which the CFS reading predicted a greater or lesser degree of stenosis than measured by arteriography.

was also evaluated as a method of identifying 70% to 99% ICA stenosis. This ratio was found in our previous retrospective series to be the most reliable for distinguishing this subset of patients.[4] When applied prospectively, it provided a sensitivity of 76.2%, specificity of 90.2%, PPV of 67.4%, NPV of 93.4%, and accuracy of 87.2%.

A concurrent prospective quality assurance review to evaluate the traditional criteria for CFS interpretation was also performed. These results are shown in Tables VII and VIII.

DISCUSSION

Criteria for interpreting the results of any diagnostic test must be determined initially by retrospective review of data from a series of patients with lesions of varying severity. These criteria should then be evaluated on subsequent groups of patients to establish their reliability. This study confirmed that 70% to 99% ICA stenosis can be identified prospectively with an accuracy comparable to that obtained retrospectively when the same criteria are applied. Lesser degrees of stenosis in the 0% to 29%, 30% to 49%, and 50% to 69% ranges, as well as occlusions, were also diagnosed prospectively with accuracies similar to those obtained retrospectively.

In our previous retrospective analysis, a PSV > 130 cm/sec and an EDV > 100 cm/sec had the best overall accuracy (95%) for differentiating between < 70% and > 70% ICA stenoses, but the sensitivity of these criteria was only 81%.[4] On the basis of PSV alone, the sensitivity in the current study was even less (78%) owing to the inclusion of eight preocclusive lesions (string signs), each with a PSV < 40 cm/sec (Table III). When a stenosis exceeds 95% diameter reduction, flow within the ICA may diminish to barely perceptible levels and is frequently seen as only a trickle of color superimposed on the B-mode image.[7] Unless the region of the ICA is surveyed carefully, the residual flow stream may be overlooked. Consequently, lesions of this severity are far more likely to be misclassified as total occlusions than as low-grade stenoses. Even when flow is detected, distortion of the waveform, broadening of the spectrum, and visualization of extensive plaque are indicative of severe disease. Because these eight preocclusive lesions were recognized easily and classified properly, the actual sensitivity of CFS for 70%

Table VII. Accuracy of CFS based on traditional criteria, prospective interpretation (n = 457)

	Arteriogram (% stenosis)					
Duplex (% stenosis)	*00 to 15*	*16 to 49*	*50 to 79*	*80 to 99*	*100*	*Total*
00 to 15	153	4	–	–	–	157
16 to 49	2	37	–	–	–	39
50 to 79	4	21	109	4	–	138
80 to 99	–	1	11	68	–	80
100	–	1	–	1	41	43
Total	159	64	120	73	41	457

Kappa (0% to 99% stenosis) = 0.840 ± 0.022; perfect agreement = 88.7%.
Kappa (for entire table) = 0.858 ± 0.019; perfect agreement = 89.3%.

Table VIII. Accuracy parameters of CFS based on traditional criteria

			Predictive value		
% Stenosis	*Sensitivity (%)*	*Specificity (%)*	*Positive (%)*	*Negative (%)*	*Accuracy (%)*
≤15 vs 16 to 99	98.4	96.2	97.7	97.5	97.6
≤49 vs 50 to 99	100.0	88.3	88.1	100.0	93.7
≤79 vs 80 to 99	94.4	96.5	85.0	98.8	96.1

Derived from Table VII. Based on 4 × 4 matrix, excludes 100% column and row.

to 99% stenosis in our current prospective study was 87% (Tables V and VI).

Aside from the eight preocclusive lesions, the majority of the 70% to 99% arteriographic stenoses that were underestimated by the new CFS criteria were "near misses" in the 70% to 80% range. Because a spectrum of ICA velocities corresponds to any given degree of stenosis, it is difficult to define criteria that are sensitive to all stenoses above a certain level without increasing the proportion of false-positive results. The velocities we adopted to identify 70% to 99% stenosis minimize the number of false-positive and false-negative scans, and provide acceptable levels of sensitivity and specificity.

Occlusion or high-grade stenosis of the contralateral ICA was the most common reason for falsely predicting 70% to 99% diameter reduction in ICAs with a lesser degree of arteriographic stenosis. In this situation, flow in the ipsilateral ICA is frequently augmented to compensate for decreased flow in the contralateral ICA, which leads to an increased flow velocity in the ipsilateral ICA. Thus, in a classification scheme based on velocities, it is not surprising that the degree of ICA stenosis in some patients with severe contralateral disease may be overestimated—a phenomenon that has been reported previously.[9] Of 36 patients with contralateral ICA occlusion, CFS criteria overestimated the severity of ipsilateral ICA stenosis in six (16.7%). Overestimation in the presence of contralateral ICA occlusion occurred more frequently in the ICAs of patients with moderate disease (50% to 69%) than it did in the ICAs of patients with lesser degrees of stenosis (<50%). Velocity data in patients with severe contralateral disease should be interpreted cautiously, and the B-mode image and degree of spectral broadening should also be considered in the estimation of stenosis severity.

Although the conclusions of the randomized CEA trials were based on outcome analysis of patients with 70% to 99% arteriographic stenosis of the ICA, routine arteriography is not only costly but also subjects the patient to additional risks. The risk of arteriography in terms of stroke alone in the North American Symptomatic Carotid Endarterectomy Trial was 0.7%[5]; in the recently reported Asymptomatic Carotid Atherosclerosis Study, the risk was 1.2%.[10] When combined with the morbidity from the surgery itself, routine preoperative arteriography increases the risk of CEA and therefore decreases its potential benefit. In a recently published series,[11] we found that 96% of our patients would have received appropriate clinical management on the basis of the results of CFS alone, and that arteriography contributed little to the decision for or against surgery. This conclusion has also been reached by other investigators.[12] Because the number of false-positive scans in the NASCET was high (60% specificity and 88% sensitivity for 70% to 99% stenosis), the investigators in this trial remain hesitant to recommend surgery on the basis of CFS findings alone.[13] Participating in that study, however, were many laboratories in which standardization and quality assurance was lacking. CFS should be used as the sole diagnostic method only when examinations are performed by accredited laboratories that are able to document a high degree of accuracy by routine quality assurance reviews.[14]

We believe that the criteria outlined in this article for identifying 70% to 99% ICA stenosis are reliable enough that, in a patient with appropriate symptoms and a technically adequate scan, CEA may be performed without confirmatory preoperative arteriography. Our results suggest that 98% of ICAs thought to have 70% to 99% stenosis would have at least 50% stenosis, 89% would have 70% to 99% stenosis, and only 2% would have diameter reductions < 50% (Table V and Fig. 1). The NPV of CFS for ≤69% ICA stenosis was 96%. If a policy of nonintervention could be adopted for lesions of this magnitude, only 4% of patients with ICAs classified as such would be denied appropriate treatment. Conversely, if the policy were liberalized to consider any symptomatic patient with > 50% diameter reduction as a potential candidate for endarterectomy, CFS would identify all patients eligible for CEA and would effectively eliminate all patients who were ineligible (Tables V and VI). Scans that are read as 50% to 69% stenosis should, however, be confirmed by arteriography or by repeat studies because an appreciable portion (17% in this series) may represent overestimations of less severe disease.

Other investigators have proposed CFS criteria for diagnosing 70% to 99% ICA stenosis. Moneta et al.[15] reported that an ICA-PSV/CCA-PSV ratio > 4.0 identified this subset of patients with a sensitivity of 91.4%, specificity of 86.5%, PPV of 75.7%, NPV of 95.6%, and an accuracy of 88.0%. The use of ratios to categorize degrees of stenosis is, in theory, attractive. Ratios potentially allow each carotid artery to act as its own control without regard for contralateral disease. In an unbranched tube, mean velocity ratios should be able to predict with accuracy the severity of any stenosis that is present. The human carotid artery, with its pulsatile flow and branch points, however, does not conform to these requirements. When applied to our data, an ICA-PSV/CCA-PSV ratio > 4.0 predicted 70% to 99% ICA stenosis with a sensitivity of only 63.6%, a specificity of 95.5%, a PPV of 77.8%, a NPV of 91.4%, and an accuracy of 89.2%. Although use of this ratio in our laboratories would result in a low number of false-positive results (high specificity), many patients with significant carotid disease would not be identified (low sensitivity).

In Moneta's report, an ICA PSV of > 325 cm/sec was found to be equally accurate (88.0%) for identifying 70% to 99% ICA stenosis. The sensitivity with this criterion was 82.8%; specificity, 90.5%; PPV, 80.0%; and NPV, 91.9%. When applied to our data, sensitivity was extremely low (only 28.8%), with a specificity of 99.0%, PPV of 85.0%, NPV of 88.0%, and an accuracy of 87.9%.

Conversely, if our criteria were applied to the patients in Moneta's series, 70% to 99% ICA stenosis would have been identified with a sensitivity and specificity of approximately 85%, PPV of 72%, NPV of 92%, and accuracy of 85%. These results are only marginally inferior to those obtained with Moneta's criteria, and may imply that the criteria we have proposed may be more widely applicable to other laboratories.

In a 1994 report, Neale et al.,[16] found that an ICA PSV > 270 cm/sec and an EDV > 110 cm/sec identified 70% to 99% ICA stenosis in their laboratory with a sensitivity of 96%, specificity of 91%, PPV of 74%, NPV of 99%, and accuracy of 93%. When applied to our patients, these criteria yielded a sensitivity of 58.8%, specificity of 98.7%, PPV of 92.2%, NPV of 90.4%, and an accuracy of 90.6%. Again, the sensitivity of Neale's criteria is low in our laboratories, suggesting that their criteria may be too stringent.

It appears that the investigators in these two studies recorded considerably higher ICA velocities in patients with 70% to 99% ICA stenosis than we observed. One possible explanation for this apparent discrepancy is that the duplex scanner used in their studies differed from the two devices we used, and may have registered higher frequency shifts for identical stenoses. To avoid this source of error, the accuracy of specific velocity criteria should be evaluated by individual laboratories with data obtained with the instruments available.

It is worthy of comment that the parameters of accuracy were marginally better when traditional criteria were used (Tables VII and VIII). Whereas 87.0% of 70% to 99% stenoses were correctly identified by the new criteria, the traditional criteria identified 94.4% of the 80% to 99% lesions. Thus, a diameter reduction of 80% may represent a more physiologic cut-off point. These observations suggest that discarding the traditional criteria may be premature.

CONCLUSION

This study verifies that an ICA PSV > 130 cm/sec and an EDV > 100 cm/sec measured with CFS predicts ≥ 70% ICA stenosis in our laboratories with an acceptable degree of accuracy. Errors most commonly occurred in patients with severe contralateral disease and in patients with borderline stenoses. The results also support the use of CFS to identify symptomatic patients who are likely to benefit from surgery. Although we believe that our findings are generally applicable, other laboratories should conduct their own quality assurance reviews before adopting the criteria that we propose.

Mary Garfield, BS, MT(ASCP), assisted in the storing and compiling of the data on which this work was based.

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DISCUSSION

Dr. Gregory L. Moneta (Portland, Ore.). This paper raises important points about data analysis, noninvasive criteria for operative threshold lesions of ICA stenosis, and variability among the various duplex machines.

I disagree somewhat with the authors' method of analyzing their data and in testing their hypothesis. Their primary purpose was to prospectively validate retrospectively determined criteria to detect a > 70% to 99% NASCET ICA stenosis. In their original paper describing the retrospective study, the authors properly excluded from analysis occluded ICAs and properly included for analysis all patent ICAs. In today's paper, occluded ICAs are included in the analysis of > 70% lesions even though they're obviously not operable. Their inclusion, however, does improve predictive value, because the authors have previously shown that they can tell ICA occlusion quite well with CFS.

Nine failures of the proposed criteria are dismissed as "obviously aberrant." These are arteries that were identified as abnormal by CFS but did not meet the velocity criteria tested in the study. The word "aberrant" can be regarded as a euphemism for "clean miss." These nine aberrant arteries were not included in the analysis, but all of the patients had angiograms that demonstrated high-grade stenosis. Eighteen other arteries that were described as having similar degrees of stenosis but that did meet the criteria tested were included in the analysis. A cynic might conclude that one criteria for inclusion in the analysis is that the results are compatible with the authors' hypothesis; however, with possibly one prominent exception, there are no cynics in Oregon!

I recalculated the authors' results according to their original methods and the methods others have used in determining sensitivity. With these recalculations, the authors' sensitivity for detecting a >70% stenosis falls from 90% to 77%. I suggest that as more studies of this type are performed that individual groups be consistent in their methods and that we all analyze the data in the same manner to facilitate comparisons.

In a broader context, I'd like to ask the authors what they consider an appropriate sensitivity and PPV for a threshold lesion to justify CEA without angiography? Should different criteria apply if the procedure is for symptomatic versus asymptomatic disease? Accepting that some variability is characteristic of CFS and angiography, are these criteria really clinically realistic?

Of course, engineering differences in duplex scanners will affect the data. The authors are correct in concluding that one should not completely depend on anyone else's data. Studies such as this one are starting points for quality assurance in individual laboratories and for debate concerning the appropriateness of CEA without preoperative angiography. It remains to be seen how to precisely implement this information in clinical practice.

Dr. Douglas B. Hood. You are correct that in the retrospective analysis we did exclude occlusions; however, we believed that it was important to include these in our prospective series because we do see a fair number of these in our labs. When analyzed with the occlusions excluded, our sensitivity did drop somewhat to 86%, but our specificity increased to 97%.

We also excluded nine patients with high-grade stenoses of 95% to 99% but very low velocities on CFS. These string signs represented about one third of our patients with this degree of stenosis. All nine of these patients were correctly identified at the time of initial reading of the CFS – mainly by the finding of a trickle of flow on the color-flow image. This illustrates the importance of reviewing the B-mode and color-flow images of the CFS and not simply using it to place the Doppler sample volume, because these images do provide very important information.

As to different criteria for asymptomatic and symptomatic patients, I believe these criteria will apply equally well to those groups of patients. However, the prospective trials evaluated different groups of patients >70% for symptomatic patients and >60% for asymptomatic. The criteria we presented today do not identify the group with >60% stenosis; however, they apply equally well to patients with symptoms and those without symptoms.

As an aside, during our retrospective analysis, we found that a PSV of >170 cm/sec in the ICA identified >60% stenosis with a sensitivity of 93% and a specificity of 89%.

For performing CEA without arteriography, the most important factor is the quality of the scan and the quality of the lab that performed the scan. It is important that the operating surgeon review the scan to determine its reliability. When using CFS to perform CEA without arteriography, it is important to have a high PPV and a high specificity so that you avoid operating on patients with a false-positive scan, and we feel that these criteria did achieve that.

As to whether strict criteria are realistic to identify these patients and select them for surgery, it is well known that even the gold standard of arteriography is not really a gold standard, but has both interobserver and intraobserver variability.

Also, a half-millimeter change in the diameter of the stenosis may change percent stenosis by 10% to 15%. So whether you estimate a stenosis at 65% or 75% may not be important.

Dr. Wesley S. Moore (Los Angeles, Calif.). Your point concerning variability not only among laboratories but between machines within the same laboratory needs to be emphasized. During the initiation of the asymptomatic carotid atherosclerosis study, which depended very heavily on CFS technology, these variables were reviewed in a prospective manner. Receiver operator curves were generated not only for each laboratory, but more specifically for each instrument within a given laboratory. It turned out that each instrument had a different velocity cut-off point for identification of stenoses ≥60%. I am curious to know whether or not you identified different cut-off points between the two machines that you had in your own lab.

The second comment has to do with the issue of assuming that the angiogram was the gold standard. You, like most other authors, have made that assumption, and therefore either affirm or are disappointed when CFS fails to confirm what you see on the angiogram. I'm aware of at least three papers that have used the lesion, as removed at the time of surgery, as the gold standard. When that's done, it turns out that a well-performed CFS more accurately correlates with the lesion (the real gold standard) than did the angiogram.

Dr. Hood. We did not generate receiver operator curves for each machine; however, when looking at the accuracy, sensitivity, and specificity values, the two machines were equally accurate with these criteria. The same criteria were used for both machines.

Arteriography, as I said, is not a perfect gold standard, but I think that it perhaps is the best gold standard that we have widely available. You noted the studies that use the actual plaque to confirm the degree of stenosis. We did not do that in this study, but it may be a better method.